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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,001	11/14/2001	Michael L. Bell	1840-045	4728
47626	7590	01/18/2005	EXAMINER	
SHELDON & MAK PC 225 SOUTH LAKE AVENUE 9TH FLOOR PASADENA, CA 91101			HAQ, SHAFIQUL	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,001

Applicant(s)

BELL ET AL.

Examiner

Shafiqul Haq

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/14/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-21 are currently pending in the instant application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a reagent for measuring target analytes in a sample, classified in class 436, and plethora of subclasses.
- II. Claims 13-17, drawn to a method of use, classified in class 435, and several subclasses.
- III. Claim 18, drawn to a Kit for assaying multiple analytes in a sample.
- IV. Claims 19-21, drawn to an apparatus for assaying analytes in a sample, classified in class 422, subclass 82.08.

2. Inventions of group I and group II are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antigen- or antibody sensor of claim 1 can be used in a materially different process such as purifying target antigen or antibody by batch purification.

3. Inventions of group I and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case the reagent of group I requires an ion sensor, which is not required in group III. The product of groups III requires an apparatus, which is not required in group I.

4. Inventions of group IV and group I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of group IV does not require the particulars of reagents of group I for patentability. The subcombination has separate utility such as the enzyme alkaline phosphatase of claim 4 of group I can be used to remove phosphate groups from DNA for cloning purposes.
5. Inventions a) group II and b) each of groups III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as it can be used to count the number and type of leukocytes (white blood cells) in a person's blood.

6. Inventions of group III and group IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of group III does not require the specific structure of the apparatus of group IV for patentability. The subcombination has separate utility such as a device for separation of analytes.
7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. §821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

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Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

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8. This application contains claims directed to the following patentably distinct species of the claimed invention.

If the reagent of group I is selected, one species must be elected from the following species groups set forth below: A or B; C, D or E; 1-7; 8-23.

If the method of group II is selected, one species must be elected from the following species group set forth below: 1-7; 8-19; 20-23.

Furthermore, if species 1. ions are chosen, select one species from group a-c. If species 8. saccharides are chosen, select one species from (1)-(4). If species 20. enzymes is chosen, select one species from i-ix.

A-E each comprise a separate invention under 35 USC 121 as being different sensors.

- (A). Ion-sensors
- (B). Metabolite-sensors
- (C). Enzyme-sensors
- (D). Antigen- or antibody-sensors
- (E). Nucleotide sensors

1-23. each comprise a separate invention under 35 USC 121 as being different analytes.

- 1. alkali metal ions
- 2. alkaline earth metal ions
- 3. ammonium
- 4. halide ions.
- 5. oxygen.
- 6. pH
- 7. carbon dioxide.
- 8. saccharides.
- 9. ammonia
- 10. urea
- 11. uric acid
- 12. cholesterol
- 13. triglycerides
- 14. ethanol
- 15. lactate
- 16. salicylate

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- 17. acetaminophen
- 18. bilirubin
- 19. creatinine
- 20. enzymes
- 21. antibodies
- 22. antigens
- 23. polynucleotide sequences

a-c each comprise a separate invention under 35 USC 121 as being different ions.

- a Sodium, potassium.
- b Calcium, magnesium.
- c Chloride & halide

(1) – (4) each comprise a separate invention under 35 USC 121 as being different different saccharides.

- (1) Glucose
- (2) Fructose
- (3) Lactose
- (4) Galactose

i-ix each comprise a separate invention under 35 USC 121 as being different enzymes

- (i) Alkaline phosphatase
- (ii) Alanine aminotransferase
- (iii) Aspartate aminotransferase
- (iv) Amylase
- (v) Cholinesterase
- (vi) Creatinine kinase
- (vii) Gamma-glutamyl transferase
- (viii) Lactate dehydrogenase
- (ix) Lipase

The claims are deemed to correspond to the species listed above in the following manner:

Species for sensor drawn to claim 1.

Species for analytes drawn to claims 1-4 & 13-16.

Species for inos drawn to 2 & 13-14.

Species for saccharides drawn to 3, 13 & 15

Species for enzymes drawn to 4 & 16

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The sensors, A-E are unrelated because they each sense different entities. The analytes 1-23 are unrelated because they have structurally diverse chemical and biological structure, different chemical properties, modes of action, different effect and reactive condition. The enzymes (i)-(ix) are unrelated as different enzymes have different modes of operation, different functions and different effects. The ions a-c are unrelated as they are different ions and their functions are different. The saccharides (1)-(4) are unrelated as the saccharides are structurally different from each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 & 13 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant

must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(1)

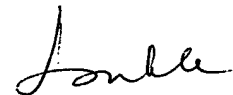
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shafiqul Haq
Patent Examiner
Art Unit 1641



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1/12/05